

## CLAIMS

That which is claimed is:

5 1. An ophthalmic lens having ophthalmically compatible inner and outer surfaces, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids, said lens comprising a polymeric material which has a high oxygen permeability and a high ion permeability, said polymeric material being formed from polymerizable materials comprising:

10 (a) at least one oxypm polymerizable material and

(b) at least one ionperm polymerizable material,

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids, and

15 wherein said lens allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids.

20 2. An ophthalmic lens of claim 1, wherein said ophthalmic lens is selected from the group consisting of contact lenses for vision correction, contact lenses for eye color modification, ophthalmic drug delivery devices, and ophthalmic wound healing devices.

3. An ophthalmic lens of claim 2, wherein said ophthalmic lens is a contact lens.

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4. An ophthalmic lens of claim 1, wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm.

5. An ophthalmic lens of claim 4, wherein said ophthalmic lens has an oxygen transmissibility of at least about 75 barrers/mm.

6. An ophthalmic lens of claim 5, wherein said ophthalmic lens has an oxygen transmissibility of at least about 87 barrers/mm.

7. An ophthalmic lens of claim 1, wherein said polymeric material comprises an ionoperm phase which extends continuously from the inner surface of the ophthalmic lens to the outer surface of the ophthalmic lens.

8. An ophthalmic lens of claim 1, wherein said polymeric material comprises an oxyperm phase which extends continuously from the inner surface of the ophthalmic lens to the outer surface of the ophthalmic lens.

9. An ophthalmic lens of claim 1, wherein said polymeric material comprises a plurality of continuous phases, including at least one oxyperm phase which extends continuously from the inner surface of the ophthalmic lens to the outer surface of the ophthalmic lens and at least one

ionoperm phase which extends continuously from the inner surface of the ophthalmic lens to the outer surface of the ophthalmic lens.

10. An ophthalmic lens of claim 1, wherein said polymeric material comprises at least one ion or water pathway which extends continuously from the inner surface of the ophthalmic lens to the outer surface of the ophthalmic lens.

11. An ophthalmic lens of claim 1, wherein said polymeric material comprises at least one oxygen pathway which extends continuously from the inner surface of the ophthalmic lens to the outer surface of the ophthalmic lens.

12. An ophthalmic lens of claim 1, wherein said polymeric material comprises a plurality of co-continuous pathways, at least one being an ion or water pathway and at least one other being an oxygen pathway, which pathways extend continuously from the inner surface of the lens to the outer surface of the lens.

13. An ophthalmic lens of claim 12, wherein said co-continuous pathways include a continuous phase of ionoperm polymeric material and a continuous phase of siloxane-containing polymeric material.

14. An ophthalmic lens of claim 12, wherein said pathways have a domain size which is less than a size which undesirably distorts visible light in an amount which is visible to the eye of the wearer.

5 15. An ophthalmic lens of claim 1, wherein said lens has an Ionoton Ion Permeability Coefficient of greater than about  $0.2 \times 10^{-6} \text{ cm}^2/\text{sec}$ .

16. An ophthalmic lens of claim 15, wherein said lens has an an Ionoton Ion Permeability Coefficient of greater than about  $0.3 \times 10^{-6} \text{ cm}^2/\text{sec}$ .

10 17. An ophthalmic lens of claim 16, wherein said lens has an an Ionoton Ion Permeability Coefficient of greater than about  $0.4 \times 10^{-6} \text{ cm}^2/\text{sec}$ .

18. An ophthalmic lens of claim 1, wherein said lens has an Ionoflux Diffusion Coefficient of  
15 greater than about  $1.5 \times 10^{-6} \text{ mm}^2/\text{min}$ .

19. An ophthalmic lens of claim 18, wherein said lens has an Ionoflux Diffusion Coefficient of greater than about  $2.6 \times 10^{-6} \text{ mm}^2/\text{min}$ .

20 20. An ophthalmic lens of claim 19, wherein said lens has an Ionoflux Diffusion Coefficient of greater than about  $6.4 \times 10^{-6} \text{ mm}^2/\text{min}$ .

21. An ophthalmic lens of claim 1, wherein said lens has a Hydrodell Water Permeability Coefficient of greater than about  $0.2 \times 10^{-6} \text{ cm}^2/\text{min}$ .

22. An ophthalmic lens of claim 21, wherein said lens has a Hydrodell Water Permeability Coefficient of greater than about  $0.3 \times 10^{-6} \text{ cm}^2/\text{min}$ .

23. An ophthalmic lens of claim 22, wherein said lens has a Hydrodell Water Permeability Coefficient of greater than about  $0.4 \times 10^{-6} \text{ cm}^2/\text{min}$ .

24. An ophthalmic lens of claim 1, wherein when hydrated, said lens has an equilibrium water content of less than about 32 weight percent when tested in accordance with the Bulk Technique.

25. An ophthalmic lens of claim 24, wherein when hydrated, said lens has an equilibrium water content of about 10 to about 30 weight percent when tested in accordance with the Bulk Technique.

26. An ophthalmic lens of claim 25, wherein when hydrated, said lens has an equilibrium water content of about 15 to about 25 weight percent when tested in accordance with the Bulk Technique.

27. An ophthalmic lens of claim 1, wherein said lens comprises a core polymeric material and an ophthalmically compatible surface which is a hydrophilic surface, wherein said surface is more hydrophilic than said core.

5 28. An ophthalmic lens of claim 27, wherein said hydrophilic surface is a hydrophilic polymeric surface coating.

29. An ophthalmic lens of claim 28, wherein said hydrophilic surface coating is applied via a plasma coating process.

10 30. An ophthalmic lens of claim 29, wherein said plasma coating is generated in the presence of a mixture of (a) a  $C_{1-6}$  alkane and (b) a gas selected from the group consisting of nitrogen, argon, oxygen, air and mixtures thereof.

15 31. An ophthalmic lens of claim 30, wherein said plasma coating is generated in the presence of a mixture of methane and air.

32. An ophthalmic lens of claim 1, wherein said oxypem polymerizable material is a siloxane-containing macromer.

33. An ophthalmic lens of claim 32, wherein said siloxane-containing macromer is a poly(dimethyl siloxane) having a number average molecular weight of at least about 800 and a glass transition temperature less than about -115 degrees Celsius.

5 34. An ophthalmic lens of claim 33, wherein said siloxane-containing macromer has a number average molecular weight of at least about 1700.

35. An ophthalmic lens of claim 32, wherein said polymeric material is formed from a polymerizable mixture comprising about 1 to about 10 weight percent of a low molecular weight  
10 siloxane-containing monomer.

36. An ophthalmic lens of claim 35, wherein said low molecular weight siloxane-containing monomer is TRIS.

15 37. An ophthalmic lens of claim 1, wherein said polymeric material is formed from a polymerizable mixture comprising:

(a) about 60 to about 85 weight percent oxypem macromer; and

(b) about 15 to about 40 weight percent ionopem monomer.

38. An ophthalmic lens of claim 37, wherein said polymeric material is formed from a polymerizable mixture comprising:

- (a) about 70 to about 82 weight percent oxypem macromer; and
- (b) about 18 to about 30 weight percent ionopem monomer.

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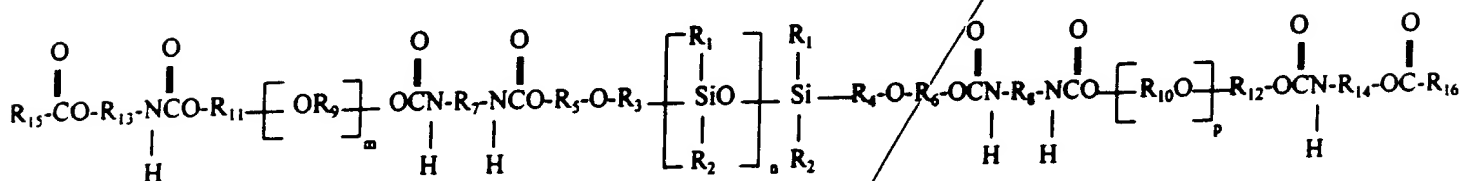
39. An ophthalmic lens of claim 1, wherein said polymeric material is formed from a polymerizable mixture comprising:

- (a) about 30 to 60 weight percent oxypem macromer;
- (b) about 20 to 40 weight percent ionopem polymerizable material; and
- (c) about 1 to 35 weight percent TRIS, based on the total lens weight.

10

40. An ophthalmic lens of claim 1, wherein said polymeric material includes a polymer composition having good optical clarity and high oxygen permeability, comprising:

(a) about 5 to about 94 dry weight percent of a macromer having the formula:



wherein:

$\text{R}_1$  and  $\text{R}_2$  are selected from  $\text{C}_1$ - $\text{C}_6$  alkyl,

$\text{R}_3$ ,  $\text{R}_4$ ,  $\text{R}_5$ , and  $\text{R}_6$  are selected from  $\text{C}_1$ - $\text{C}_6$  alkylene,

$\text{R}_7$  and  $\text{R}_8$  are selected from linear or branched alkylene and bivalent cycloalkylene,

$\text{R}_9$ ,  $\text{R}_{10}$ ,  $\text{R}_{11}$ , and  $\text{R}_{12}$  are selected from  $\text{C}_1$ - $\text{C}_2$  alkylene,

$\text{R}_{13}$  and  $\text{R}_{14}$  are selected from  $\text{C}_1$ - $\text{C}_6$  alkylene,

$\text{R}_{15}$  and  $\text{R}_{16}$  are selected from linear or branched lower alkenylene,

$m$  and  $p$ , independently of one another, are about 3 to about 44, and

$n$  is about 13 to about 80,

wherein said macromer has a number-average molecular weight of 2000 to 10,000;

(b) about 5 to about 60 weight percent of an acrylated or methacrylated siloxane monomer;

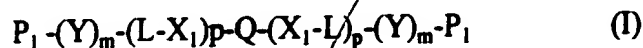
(c) about 1 to about 30 weight percent of an acrylate or methacrylate monomer; and

(d) 0 to 5 weight percent cross-linking agent;

wherein said weight percentages are based upon the dry weight of the polymer components.

41. An ophthalmic lens of claim 40, wherein said lens is a contact lens.

42. An ophthalmic lens of claim 1, wherein said polymeric material comprises a polymer formed by polymerization of at least one macromer of formula (I):



where each  $P_1$ , independently of the others, is a free-radical-polymerizable group;

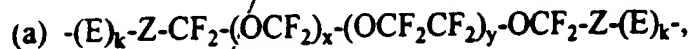
each  $Y$ , independently of the others, is  $-\text{CONHCOO}-$ ,  $-\text{CONHCONH}-$ ,  $-\text{OCONHCO}-$ ,  $-\text{NHCONHCO}-$ ,  $-\text{NHCO}-$ ,  $-\text{CONH}-$ ,  $-\text{NHCONH}-$ ,  $-\text{COO}-$ ,  $-\text{OCO}-$ ,  $-\text{NHCOO}-$  or  $-\text{OCONH}-$ ;

$m$  and  $p$ , independently of one another, are 0 or 1;

each  $L$ , independently of the others, is a divalent radical of an organic compound having up to 20 carbon atoms;

each  $X_1$ , independently of the others, is  $-\text{NHCO}-$ ,  $-\text{CONH}-$ ,  $-\text{NHCONH}-$ ,  $-\text{COO}-$ ,  $-\text{OCO}-$ ,  $-\text{NHCOO}-$  or  $-\text{OCONH}-$ ; and

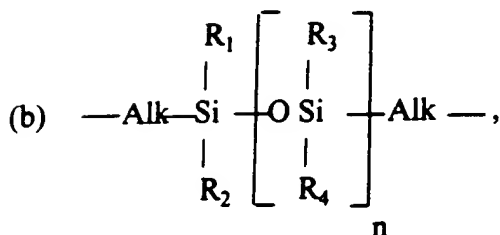
$Q$  is a bivalent polymer fragment consisting of the segments:



where  $x+y$  is a number in the range of from 10 to 30;

each  $Z$ , independently of the others, is a divalent radical having up to 12 carbon atoms or  $Z$  is a bond;

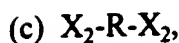
each E, independently of the others, is  $-(\text{OCH}_2\text{CH}_2)_q-$ , where q has a value of from 0 to 2, and where the link -Z-E- represents the sequence  $-Z-(\text{OCH}_2\text{CH}_2)_q-$ ; and k is 0 or 1;



where n is an integer from 5 to 100;

Alk is alkylene having up to 20 carbon atoms;

80-100% of the radicals  $\text{R}_1$ ,  $\text{R}_2$ ,  $\text{R}_3$  and  $\text{R}_4$ , independently of one another, are alkyl and 0-20% of the radicals  $\text{R}_1$ ,  $\text{R}_2$ ,  $\text{R}_3$  and  $\text{R}_4$ , independently of one another, are alkenyl, aryl or cyanoalkyl; and



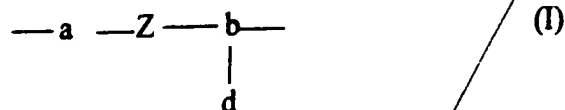
where R is a divalent organic radical having up to 20 carbon atoms, and

each  $\text{X}_2$ , independently of the others, is  $-\text{NHCO}-$ ,  $-\text{CONH}-$ ,  $-\text{NHCONH}-$ ,  $-\text{COO}-$ ,  $-\text{OCO}-$ ,  $-\text{NHCOO}-$  or  $\text{OCONH}-$ ;

with the provisos that there must be at least one of each segment (a), (b), and (c) in Q, that each segment (a) or (b) has a segment (c) attached to it, and that each segment (c) has a segment (a) or (b) attached to it.

43. An ophthalmic lens of claim 42, wherein said lens is a contact lens.

44. An ophthalmic lens of claim 1, wherein said polymeric material comprises a polymer, which polymer is produced by polymerizing at least one macromer comprising at least one segment of formula (I)



in which (a) is a polysiloxane segment,

(b) is a polyol segment which contains at least 4 C atoms,

Z is a segment (c) or a group  $X_1$ ,

(c) is defined as  $X_2\text{-R-X}_2$ , wherein

R is a bivalent radical of an organic compound having up to 20 C atoms and

each  $X_2$  independently of the other is a bivalent radical which contains at least one carbonyl group,

$X_1$  is defined as  $X_2$ , and

(d) is a radical of the formula (II):



in which  $P_1$  is a group which can be polymerized by free radicals;

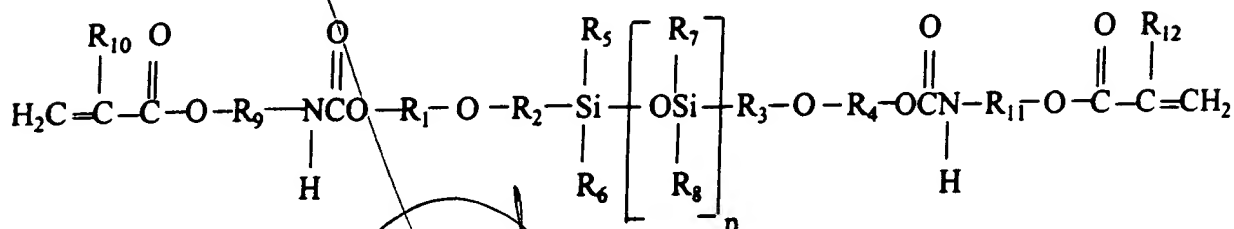
Y and  $X_3$  independently of one another are a bivalent radical which contains at least one carbonyl group;

k is 0 or 1; and

L is a bond or a divalent radical having up to 20 C atoms of an organic compound.

45. An ophthalmic lens of claim 44 which is a contact lens.

46. An ophthalmic lens of claim 1, wherein said polymeric material comprises a polymer, which  
 5 polymer is produced by polymerizing at least one macromer of the formula:



15 where  $n$  is an integer from about 5 to about 500,

$\text{R}_1$ ,  $\text{R}_2$ ,  $\text{R}_3$ , and  $\text{R}_4$ , independently of one another, are lower alkylene,

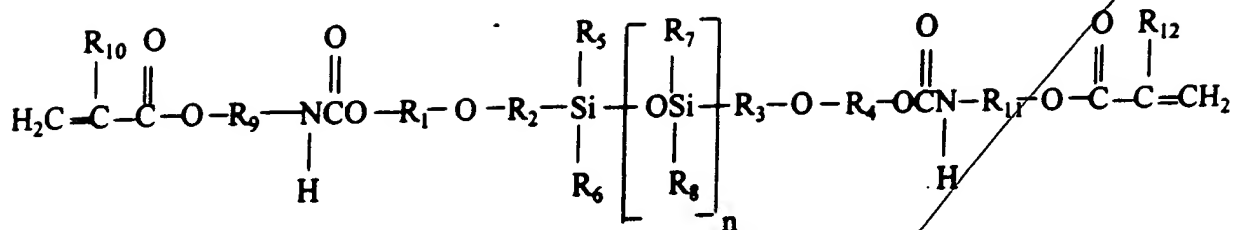
$\text{R}_5$ ,  $\text{R}_6$ ,  $\text{R}_7$ , and  $\text{R}_8$  are, independently of one another, are alkyl,

$\text{R}_9$  and  $\text{R}_{11}$  are alkylene, and

20  $\text{R}_{10}$  and  $\text{R}_{12}$  are methyl or hydrogen.

47. An ophthalmic lens of claim 46, wherein said polymeric material is formed by  
 polymerization of a prepolymer mixture, which, in weight percentages based on total mixture  
 weight, comprises:

25 (a) about 45 to about 65 percent of a siloxane-containing macromer of the formula:



where  $n$  is an integer from about 5 to about 500,

$\text{R}_1$ ,  $\text{R}_2$ ,  $\text{R}_3$ , and  $\text{R}_4$ , independently of one another, are lower alkylene,

$\text{R}_5$ ,  $\text{R}_6$ ,  $\text{R}_7$ , and  $\text{R}_8$  are, independently of one another, are alkyl,

$\text{R}_9$  and  $\text{R}_{11}$  are alkylene, and

$\text{R}_{10}$  and  $\text{R}_{12}$  are methyl or hydrogen;

(b) about 5 to about 25 percent TRIS; and

(c) about 20 to about 40 percent ionoperm monomer

48. An ophthalmic lens of claim 47 which is a contact lens.

49. An ophthalmic lens of claim 1, wherein said lens allows oxygen transmission in an amount sufficient to prevent any clinically significant corneal swelling during a period of extended, continuous contact with ocular tissue and ocular fluids.

50. An ophthalmic lens of claim 1, wherein said lens produces, after wear of about 24 hours, including normal sleep periods, less than about 8% corneal swelling.

51. An ophthalmic lens of claim 50, wherein said lens produces, after wear of about 24 hours, including normal sleep periods, less than about 6% corneal swelling.

52. An ophthalmic lens of claim 51, wherein said lens produces, after wear of about 24 hours, including normal sleep periods, less than about 4% corneal swelling.

53. An ophthalmic lens of claim 1, wherein said period of extended continuous contact is at least 24 hours.

54. An ophthalmic lens of claim 53, wherein said period of extended continuous contact is at least 4 days.

55. An ophthalmic lens of claim 54, wherein said period of extended continuous contact is at least 7 days.

56. An ophthalmic lens of claim 55, wherein said period of extended continuous contact is at least 14 days.

57. An ophthalmic lens of claim 56, wherein said period of extended continuous contact is at least 30 days.

58. An ophthalmic lens of claim 1, wherein said lens has a tensile modulus of 3 MPa or less.

59. An ophthalmic lens of claim 1, wherein said lens has a short relaxation time constant of greater than about 3.5 seconds.

5 60. An ophthalmic lens of claim 59, wherein said lens has an Ionoton Ion Permeability Coefficient, P, of greater than about  $0.2 \times 10^{-6} \text{ cm}^2/\text{sec}$ .

61. An ophthalmic lens of claim 59, wherein said lens has an Ionoflux Diffusion Coefficient of greater than about  $2.6 \times 10^{-6} \text{ mm}^2/\text{min}$ .

10 62. An ophthalmic lens of claim 59, wherein said lens has a Hydrodell Water Permeability Coefficient of greater than about  $0.2 \times 10^{-6} \text{ cm}^2/\text{min}$ .

15 63. An ophthalmic lens of claim 1, wherein the polymeric material has a  $\tan \delta$  above about 0.25 at about 10 Hz.

20 64. An ophthalmic lens of claim 1, wherein said lens has an Ionoton Ion Permeability Coefficient of greater than about  $0.3 \times 10^{-6} \text{ cm}^2/\text{sec}$ , a tensile modulus of 3 MPa or less, and a short relaxation time constant of greater than about 3.5 seconds.

65. An ophthalmic lens of claim 1, wherein said lens has an Ionoflux Diffusion Coefficient of greater than about  $2.6 \times 10^{-6}$  mm<sup>2</sup>/min., a tensile modulus of 3 MPa or less, and a short relaxation time constant of greater than about 3.5 seconds.

5 66. An ophthalmic lens of claim 1, wherein said lens has a Hydrodell Water Permeability Coefficient of greater than about  $0.3 \times 10^{-6}$  cm<sup>2</sup>/min., a tensile modulus of 3 MPa or less, and a short relaxation time constant of greater than about 3.5 seconds.

10 67. An ophthalmic lens of claim 1, wherein said lens comprises a core polymeric material and an ophthalmically compatible surface which is a hydrophilic surface, wherein:

said surface is more hydrophilic than said core,

said period of extended continuous contact period is at least 7 days,

said core material has an Ionoton Ion Permeability Coefficient of greater than about  $0.3 \times 10^{-6}$  cm<sup>2</sup>/sec, a tensile modulus of 3 MPa or less, and a short relaxation time constant of greater  
15 than about 3.5 seconds,

said lens has an equilibrium water content of about 10 to about 30 weight percent when tested in accordance with the Bulk Technique,

said lens has an oxygen permeability of at least 70 barrers/mm, and

said lens is an extended-wear contact lens.

20 68. An ophthalmic lens of claim 1, wherein said lens comprises a core polymeric material and an ophthalmically compatible surface which is a hydrophilic surface, wherein:

said surface is more hydrophilic than said core,

said period of extended continuous contact period is at least 7 days,

said core material has an Ionoflux Diffusion Coefficient of greater than about  $2.6 \times 10^{-6}$  mm<sup>2</sup>/min., a tensile modulus of 3 MPa or less, and a short relaxation time constant of greater than about 3.5 seconds,

said lens has an equilibrium water content of about 10 to about 30 weight percent when tested in accordance with the Bulk Technique,

said lens has an oxygen permeability of at least 70 barrers/mm, and

said lens is an extended-wear contact lens.

69. An ophthalmic lens of claim 1, wherein said lens comprises a core polymeric material and an ophthalmically compatible surface which is a hydrophilic surface, wherein:

said surface is more hydrophilic than said core,

said period of extended continuous contact period is at least 7 days,

said core material has a Hydrodell Water Permeability Coefficient of greater than about  $0.2 \times 10^{-6}$  cm<sup>2</sup>/min., a tensile modulus of 3 MPa or less, and a short relaxation time constant of greater than about 3.5 seconds,

said lens has an equilibrium water content of about 10 to about 30 weight percent when tested in accordance with the Bulk Technique,

said lens has an oxygen permeability of at least 70 barrers/mm, and

said lens is an extended-wear contact lens.

70. An ophthalmic lens, comprising an inner and outer surface, wherein said inner surface is adapted to rest immediately adjacent to the human cornea, wherein said lens has the following properties:

- (a) an oxygen permeability from said inner to said outer surface sufficient to prevent substantial corneal swelling during a period of extended wear;
- (b) ophthalmic compatibility during a period of extended, continuous, intimate contact with the ocular environment; and
- (c) ion or water permeability sufficient to allow lens movement on the eye in an amount sufficient to sustain corneal health and wearer comfort.

<sup>2</sup>  
~~71~~. An ophthalmic lens of claim <sup>1</sup>~~70~~, wherein said period of extended wear is at least 24 hours.

<sup>3</sup>  
~~72~~. An ophthalmic lens of claim <sup>2</sup>~~71~~, wherein said lens produces, after wear of about 24 hours, including normal sleep periods, less than about 8% corneal swelling.

<sup>4</sup>  
~~73~~. An ophthalmic lens of claim <sup>3</sup>~~72~~, wherein said lens produces, after wear of about 24 hours, including normal sleep periods, less than about 6% corneal swelling.

<sup>5</sup>  
~~74~~. An ophthalmic lens of claim <sup>4</sup>~~73~~, wherein said lens produces, after wear of about 24 hours, including normal sleep periods, less than about 4% corneal swelling.

<sup>6</sup>  
~~75~~. An ophthalmic lens of claim <sup>2</sup>~~71~~, wherein said extended period of wear is at least 4 days.

- 7 <sup>7</sup> 76. An ophthalmic lens of claim <sup>64</sup> 75, wherein said extended period of wear is at least 7 days.
- 6 <sup>6</sup> 77. An ophthalmic lens of claim <sup>77</sup> 76, wherein said lens produces, after wear of about 7 days,  
5 including normal sleep periods, less than about 10% corneal swelling.
- 7 <sup>7</sup> 78. An ophthalmic lens of claim <sup>48</sup> 77, wherein said lens produces, after wear of about 7 days,  
including normal sleep periods, less than about 7% corneal swelling.
- 10 <sup>10</sup> 79. An ophthalmic lens of claim <sup>19</sup> 78, wherein said lens produces, after wear of about 7 days,  
including normal sleep periods, less than about 5% corneal swelling.
- 8 <sup>8</sup> 80. An ophthalmic lens of claim <sup>11</sup> 79, wherein said period of extended wear is at least 14 days.
- 15 <sup>12</sup> 81. An ophthalmic lens of claim <sup>11</sup> 80, wherein said extended period of wear is at least 30 days.
- MM 3/30/98 <sup>13</sup> 82. An ophthalmic lens of claim <sup>11</sup> 80, wherein said oxygen permeability (Dk) is at least <sup>80</sup> 70  
barrers/mm.
- 20 <sup>14</sup> 83. An ophthalmic lens of claim <sup>11</sup> 80, wherein said lens has a tensile modulus of 1.5 MPa or less.

15 ~~84.~~ An ophthalmic lens of claim ~~70~~, wherein said lens has a short relaxation time constant of greater than about 3.5 seconds.

Sub 85. An ophthalmic lens of claim 1, wherein the polymeric material has a  $\tan \delta$  above about 0.25 at about 10 Hz.

17 ~~86.~~ An ophthalmic lens of claim ~~70~~, wherein said lens has an Ionoton Ion Permeability Coefficient of at least about  $\overset{0.3}{\underset{\Delta}{0.2}} \times 10^{-6} \text{ cm}^2/\text{sec}$ .

10 A 18 ~~87.~~ An ophthalmic lens of claim ~~70~~, wherein said lens has an Ionoflux Diffusion Coefficient of greater than about  $\overset{2.6}{\underset{\Delta}{1.5}} \times 10^{-6} \text{ mm}^2/\text{min}$ . ✓

11 19 ~~88.~~ An ophthalmic lens of claim ~~70~~, wherein said lens has a Hydrodell Water Permeability Coefficient of greater than about  $0.2 \times 10^{-6} \text{ cm}^2/\overset{\text{sec}}{\underset{\Delta}{\text{min}}}$ .

15 ~~89.~~ An ophthalmic lens of claim ~~70~~, wherein said extended period of wear is at least 24 hours and said oxygen transmissibility is at least 80 barrers/mm, and wherein said lens has a tensile modulus of 1.5 MPa or less, a short relaxation time constant of 1.4 to 10 seconds, and an Ionoton Ion Permeability Coefficient of at least  $0.2 \times 10^{-6} \text{ cm}^2/\text{sec}$ .

20 ~~90.~~ An ophthalmic lens of claim ~~70~~, wherein said extended period of wear is at least 4 days and said oxygen permeability (Dk) is at least 90 barrers/mm, and wherein said lens has a tensile

modulus of 1.5 MPa or less, a short relaxation time constant of greater than about 3.5 seconds,  
and an Ionoton Ion Permeability Coefficient of at least  $0.4 \times 10^{-6} \text{ cm}^2/\text{sec}$

22. ~~91.~~ An ophthalmic lens of claim ~~70~~, wherein said extended period of wear is at least 4 days and  
said oxygen permeability (Dk) is at least 90 barrers/mm, and wherein said lens has a tensile  
modulus of 1.5 MPa or less, a short relaxation time constant of greater than about 3.5 seconds,  
and an Ionoflux Diffusion Coefficient of greater than about  $1.5 \times 10^{-6} \text{ mm}^2/\text{min}$ .

23. ~~92.~~ An ophthalmic lens of claim ~~70~~, wherein said extended period of wear is at least 4 days and  
said oxygen permeability (Dk) is at least 90 barrers/mm, and wherein said lens has a tensile  
modulus of 1.5 MPa or less, a short relaxation time constant of greater than about 3.5 seconds,  
and a Hydrodell Water Permeability Coefficient of greater than about  $0.2 \times 10^{-6} \text{ cm}^2/\text{min}^{\text{sec}}$ .

93. A method of using a contact lens as an extended wear lens, said lens having ophthalmically  
compatible inner and outer surfaces, said lens being suited to extended periods of wear in  
continuous, intimate contact with ocular tissue and ocular fluids, said lens comprising a  
polymeric material which has a high oxygen permeability and a high water permeability, said  
polymeric material being formed from polymerizable materials including:

- (a) at least one oxypem polymerizable; and
- (b) at least one ionopem polymerizable,

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids, and

wherein said lens allows ion permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids,

said method comprising the steps of:

- (a) applying said lens to the ocular environment; and
- (b) allowing said lens to remain in intimate contact with the ocular environment for a

first period of at least 24 hours.

94. A method of claim 93, further including the steps of:

- (c) removing said lens from the ocular environment;
- (d) disinfecting or cleaning said lens;
- (e) re-applying said lens to the ocular environment; and
- (f) allowing said lens to remain in intimate contact with the ocular environment for a

second period of at least 24 hours.

95. A method of claim 93, wherein said first intimate contact period is at least 4 days.

96. A method of claim 94, wherein said first and second intimate contact periods are at least 4 days.

97. A method of claim 95, wherein said first intimate contact period is at least 7 days.

98. A method of claim 96, wherein said first and second intimate contact periods are at least 7  
5 days.

99. A method of claim 97, wherein said first intimate contact period is at least 14 days.

100. A method of claim 98, wherein said first and second intimate contact periods are at least 14  
10 days.

101. A method of claim 99, wherein said first intimate contact period is at least 30 days.

102. A method of claim 100, wherein said first and second intimate contact periods are at least  
15 30 days.

103. An ophthalmic lens of claim 93, wherein said lens produces, after wear of about 24 hours,  
including normal sleep periods, less than about 8% corneal swelling.

20 104. An ophthalmic lens of claim 103, wherein said lens produces, after wear of about 24 hours,  
including normal sleep periods, less than about 6% corneal swelling.

105. An ophthalmic lens of claim 104, wherein said lens produces, after wear of about 24 hours, including normal sleep periods, less than about 4% corneal swelling.

106. An ophthalmic lens of claim 93, wherein said lens produces, after wear of about 7 days, including normal sleep periods, less than about 10% corneal swelling.

107. An ophthalmic lens of claim 106, wherein said lens produces, after wear of about 7 days, including normal sleep periods, less than about 7% corneal swelling.

108. An ophthalmic lens of claim 107, wherein said lens produces, after wear of about 7 days, including normal sleep periods, less than about 5% corneal swelling.

109. A method of forming a biocompatible lens having high oxygen permeability and high water permeability, said method comprising the steps of:

(a) forming a core material including:

(1) at least one continuous pathway from front curve to base curve surfaces for oxygen transmission therethrough, and

(2) at least one continuous pathway from front curve to base curve surfaces for water transmission therethrough; and

(b) altering the surface of said core material to produce a surface which is more hydrophilic than said core material,

whereby said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids, and

whereby said lens allows ion permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids.

110. A method of claim 109, wherein said ophthalmic lens has an oxygen permeability of at least 70 barrers/mm.

111. A method of claim 110, wherein said ophthalmic lens has an oxygen permeability of at least 87 barrers/mm.

112. A method of claim 109, wherein said intimate contact period is at least 24 hours.

113. A method of claim 112, wherein said intimate contact period is at least 7 days.

114. A method of claim 109, wherein said lens has an Ionoton Ion Permeability Coefficient of at least about  $0.3 \times 10^{-6} \text{ cm}^2/\text{sec}$ .

115. An ophthalmic lens of claim 109, wherein said lens has an Ionoflux Diffusion Coefficient of greater than about  $1.5 \times 10^{-6} \text{ mm}^2/\text{min}$ .

116. An ophthalmic lens of claim 109, wherein said lens has a Hydrodell Water Permeability Coefficient of greater than about  $0.2 \times 10^{-6} \text{ cm}^2/\text{min}$ .

5 117. A method of claim 111, wherein said intimate contact period is at least 7 days.

118. A method of claim 112, wherein said intimate contact period is at least 14 days.

10 119. A method of claim 118, wherein said surface altering comprises plasma treating said surface to render said surface more hydrophilic than said core.

120. An ophthalmic lens having ophthalmically compatible inner and outer surfaces, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids, said lens comprising a polymeric material which has a high oxygen permeability and a high ion permeability, said polymeric material being formed from polymerizable materials  
15 comprising at least one polymerizable material comprising:

(a) at least one oxyporm segment; and

(b) at least one ionoporm segment,

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal  
20 health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids, and

wherein said lens allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids.

5 121. An ophthalmic lens of claim 120, wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm.

122. An ophthalmic lens of claim 121, wherein said ophthalmic lens has an oxygen transmissibility of at least about 75 barrers/mm.

10 123. An ophthalmic lens of claim 122, wherein said ophthalmic lens has an oxygen transmissibility of at least about 87 barrers/mm.

124. An ophthalmic lens of claim 120, wherein said lens has an Ionoton Ion Permeability Coefficient of greater than about  $0.2 \times 10^{-6} \text{ cm}^2/\text{sec}$ .

15 125. An ophthalmic lens of claim 120, wherein said lens has an Ionoflux Diffusion Coefficient of greater than about  $1.5 \times 10^{-6} \text{ mm}^2/\text{min}$ .

20 126. An ophthalmic lens of claim 120, wherein said lens has a Hydrodell Water Permeability Coefficient of greater than about  $0.2 \times 10^{-6} \text{ cm}^2/\text{min}$ .

127. A method of screening an ophthalmic lens for utility as an extended-wear lens, said method comprising the steps of:

(a) allowing said lens to be fully hydrated by allowing said lens to equilibrate in a saline solution;

5 (b) testing the lens to determine a factor which is a function of the oxygen transmissibility of said lens;

(c) testing the lens to determine a factor which is a function of the ion or water permeability of said lens; and

10 (d) selecting said lens as an extended-wear lens if said oxygen transmissibility factor and said water or ion permeability factor are both above predetermined limits which are established to ensure good corneal health and wearer comfort when said lens is in intimate contact with a human eye for a period of continuous, extended wear of at least 24 hours.

15 128. A screening method of claim 127, wherein said ion permeability factor is the Ionoton Ion Permeability Coefficient.

129. A screening method of claim 128, wherein said Ionoton Ion Permeability Coefficient is greater than about  $0.3 \times 10^{-6} \text{ cm}^2/\text{sec}$ .

20 130. A screening method of claim 127, wherein said ion permeability factor is the Ionoflux Diffusion Coefficient.

131. A screening method of claim 130, wherein said Ionoflux Diffusion Coefficient is greater than about  $2.6 \times 10^{-6} \text{ mm}^2/\text{min}$ .

132. A screening method of claim 127, wherein said water permeability factor is the Hydrodell Water Permeability Coefficient.

133. A screening method of claim 132, wherein said Hydrodell Water Permeability Coefficient is greater than about  $0.3 \times 10^{-6} \text{ cm}^2/\text{min}$

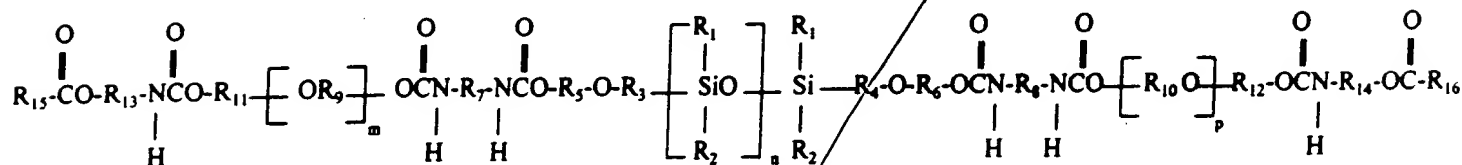
134. A screening method of claim 129, wherein said oxygen transmissibility factor is the Dk and the limit is 70 barrers/mm.

135. A screening method of claim 131, wherein said oxygen transmissibility factor is the Dk and the limit is 70 barrers/mm.

136. A screening method of claim 133, wherein said oxygen transmissibility factor is the Dk and the limit is 70 barrers/mm.

137. A polymer composition having good optical clarity and high oxygen permeability, comprising:

(a) about 5 to about 94 dry weight percent of a macromer having the formula:



wherein:

R<sub>1</sub> and R<sub>2</sub> are selected from C<sub>1</sub>-C<sub>6</sub> alkyl,

R<sub>3</sub>, R<sub>4</sub>, R<sub>5</sub>, and R<sub>6</sub> are selected from C<sub>1</sub>-C<sub>6</sub> alkylene,

R<sub>7</sub> and R<sub>8</sub> are selected from linear or branched alkylene and bivalent cycloalkylene,

R<sub>9</sub>, R<sub>10</sub>, R<sub>11</sub>, and R<sub>12</sub> are selected from C<sub>1</sub>-C<sub>2</sub> alkylene,

R<sub>13</sub> and R<sub>14</sub> are selected from C<sub>1</sub>-C<sub>6</sub> alkylene,

R<sub>15</sub> and R<sub>16</sub> are selected from linear or branched lower alkenylene,

m and p, independently of one another, are about 3 to about 44, and

n is about 13 to about 80,

wherein said macromer has a number-average molecular weight of 2000 to 10,000;

(b) about 5 to about 60 weight percent of an acrylated or methacrylated siloxane monomer;

(c) about 1 to about 30 weight percent of an acrylate or methacrylate monomer; and

(d) 0 to 5 weight percent cross-linking agent;

wherein said weight percentages are based upon the dry weight of the polymer components.

138. A polymer of claim 137, wherein said siloxane monomer is 3-methacryloxypropyltris (trimethylsiloxy)silane.

139. A polymer of claim 137, comprising:

- (a) 70 to 90 weight percent of said macromer;
- (b) 8 to 20 weight percent of said siloxane monomer;
- (c) 1 to 5 weight percent hydrophilic monomer; and
- (d) 0 to 2 weight percent cross-linking agent.

140. A polymer of claim 137, comprising about 10 to about 50 weight percent water.

141. A polymer of claim 140, wherein said water content is about 10 to about 30 weight percent.

142. A polymer of claim 141, wherein said water content is about 15 to about 22 weight percent.

143. A polymer of claim 139, comprising about 80 to 84 weight percent of said polysiloxane macromer.

144. A polymer of claim 139, comprising about 12 to 15 weight percent methacryloxypropyltris (trimethylsiloxy)silane.

145. A polymer of claim 137, wherein said acrylate or methacrylate component is 2-hydroxyethyl methacrylate.

146. A polymer of claim 140, comprising about 3 to about 4 weight percent of 2-hydroxyethyl methacrylate.

147. A polymer of claim 137, wherein said cross-linking agent is ethylene glycol dimethacrylate.

148. A polymer of claim 147, comprising about 0.7 to 1.2 weight percent ethylene glycol dimethacrylate

149. A polymer of claim 137, comprising:

- (a) about 80 to about 84 weight percent polysiloxane macromer;
- (b) about 12 to about 15 weight percent methacryloxypropyltris(trimethylsiloxy)silane;
- (c) about 3 to about 4 weight percent 2-hydroxyethyl methacrylate; and
- (d) about 0.7 to 1.2 weight percent ethylene glycol dimethacrylate.

150. A polymer of claim 149 having about 15 to about 22 weight percent water, based on total polymer weight.

151. A contact lens, comprising the polymer of claim 137.

152. A contact lens of claim 151, having a  $D_k$  greater than 80 barrers and a water content of about 10 to 30 weight percent.

5 153. A contact lens, comprising the polymer of claim 139.

154. A contact lens, comprising the polymer of claim 150.

10 155. A contact lens of claim 154, having a  $D_k$  greater than 80 barrers and a water content of about 10 to 30 weight percent.

156. A method of forming a molded polymeric article suitable for ophthalmic applications, comprising the steps of:

15 (a) contacting a poly(dialkylsiloxane) dialkanol with a diisocyanate compound in the presence of a first catalyst at conditions sufficient to cause reaction of said dialkanol with said diisocyanate, thereby forming a first mixture;

(b) contacting said first mixture with poly(alkylene glycol), a second catalyst, and sufficient solvent to ensure mixture homogeneity, thereby forming a second mixture;

20 (c) evaporating sufficient solvent from said second mixture to generate a third mixture having a solids content of about 40 to 60 weight percent;

(d) adding isocyanatoalkyl methacrylate to said third mixture, thereby forming a fourth mixture containing a polysiloxane macromer;

(e) adding to said fourth mixture 3-methacryloxypropyltris(dimethylsiloxy)silane (TRIS), a hydrophilic monomer, a cross-linking agent and a photoinitiator, thereby forming a fifth mixture;

(f) placing said fifth mixture into a mold; and

5 (g) applying sufficient radiation to said fifth mixture to copolymerize the polymerizable material contained therein, thereby forming said polymeric material into a molded polymeric article.

157. A method as recited in claim 156, wherein said molded polymeric article is a contact lens.

10 158. A method of claim 156, comprising the steps of:

(a) contacting poly(dimethylsiloxane) dialkanol with isophorone diisocyanate in the presence of dibutyltin dilaurate at conditions sufficient to cause reaction of said dialkanol with said diisocyanate, thereby forming a first mixture;

15 (b) contacting said first mixture with poly(ethylene glycol), dibutyltin dilaurate, and sufficient solvent to ensure mixture homogeneity, thereby forming a second mixture;

(c) evaporating sufficient solvent from said second mixture to generate a third mixture having a solids content of about 40 to 60 weight percent;

20 (d) adding isocyanatoethyl methacrylate to said third mixture, thereby forming a fourth mixture containing a polysiloxane macromer;

(e) adding to said fourth mixture 3-methacryloxypropyltris(dimethylsiloxy)silane, 2-hydroxyethyl methacrylate, ethylene glycol dimethacrylate and a photoinitiator, thereby forming a fifth mixture;

(f) placing said fifth mixture into a mold; and

5 (g) applying sufficient radiation to copolymerize said polysiloxane macromer, TRIS, HEMA, and EGDMA, thereby forming said polymeric material into a molded polymeric article.